



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FILE COPY

May 28, 1999

Robert S. Milanese, President
National Association of
Pharmaceutical Manufacturers
320 Old Country Road
Garden City, New York 11530-1752

Dear Mr. Milanese:

Your petition requesting the Food and Drug Administration to codify the existing FDA practice to apply scientific judgment in determining whether the active ingredients in two drug products are the "same as," or identical, was received by this office on 5/27/99. It was assigned docket number 99P-1658 CP 1 and it was filed on 5/27/99. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Jennie C. Butler
Dockets Management Branch

99P-1658

ACK1